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| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary) | | Application Number | 10/721,022 |
| | | Filing Date | November 25, 2003 |
| | | First Named Inventor | Lukas-Laskey et al. |
| | | Art Unit | 1614 |
| | | Examiner Name | P. Spivack |
| Sheet 1 of 1 | Attorney Docket Number | 04012.0384-00000 | |

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| PS | | CLELAND et al., "Clinical trials update from the American College of Cardiology: darbepoetin alfa, ASTEROID, UNIVERSE, paediatric carvedilol, UNLOAD and ICELAND," European Journal of Heart Failure, 8, pp. 326-329, 2006. | |
| PS | | SHADDY et al., "The pediatric randomized carvedilol trial in children with chronic heart failure: Rationale and design," American Heart Journal, vol. 144, no. 3, pp. 383-389, September 2002. | |
| PS | | Summary Report, Study No.: SK&F-105517/321, "A Multicenter, placebo-controlled, 8-month study of the effect of twice daily carvedilol in children with congestive heart failure due to systemic ventricular systolic dysfunction," pp. 1-9, July 2006. | |
| PS | | Clinical Study Report, Study No.: SK&F-105517/321, "A Multicenter, placebo-controlled, 8-month study of the effect of twice daily carvedilol in children with congestive heart failure due to systemic ventricular systolic dysfunction," abstract and cover pp. 1-4 and Clinical Study Report pp. 1-238, 266, 342-360, July 17, 2006. | |
| PS | | Summary Report, Study No.: SK&F-105517/396, "A Multicenter Open-label Extension Study to Evaluate the Safety of Twice Daily Oral Carvedilol in Pediatric Subjects with Chronic Heart Failure," abstract and cover pages pp. 1-4, 2005. | |
| PS | | Clinical Study Report, Study No.: SK&F-105517/396, "A Multicenter Open-label Extension Study to Evaluate the Safety of Twice Daily Oral Carvedilol in Pediatric Subjects with Chronic Heart Failure," abstract and cover pages pp. 1-4 and Clinical Study Report pp. 1-135., August 2006. | |

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| Examiner Signature | P. Spivack | Date Considered | 11/4/06 |
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